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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,519	09/18/2000	Michael C. Barney	660005.98757	4670

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 02/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/664,519	BARNEY ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15,17-23 and 25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15, 17-23 and 25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed December 7, 2004 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 15, 17-23 and 25 are pending.

Applicants' amendment filed December 7, 2004 is acknowledged, and Applicants' response has been fully considered. Claims 1, 3-8, 12 and 14 have been amended. Thus, claims 15, 17-23 and 25 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 1, 3-8, 12 and 14 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's cancellation of the claim in the amendment filed December 7, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 15, 17-23 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 15, 17-23 and 25 are directed to a method for affecting the growth of *Staphylococcus aureus* in the vaginal area with a compound of hexahydro beta acids, hexahydro beta salts, tetrahydroiso alpha acids or tetrahydroiso alpha salts, in an amount effective to kill, inhibit or control the growth of *S. aureus* without preventing the growth of *lactobacillus* at a pH of 4.5-5.0, wherein the concentration of the compound is about 0.2 to 25 ppm (claims 15 and 17-22); and a product comprising an absorbent material and a compound of hexahydro beta acids, hexahydro beta salts, tetrahydroiso alpha acids or tetrahydroiso alpha salts, in an amount effective to kill, inhibit or control the growth of *S. aureus* without preventing the growth of *lactobacillus* at a pH of 4.5-5.0, wherein the concentration of the compound is about 0.2 to 25 ppm (claims 23, and 25). The specification indicates the hop acids tetrahydroiso alpha and hexahydro beta have different bacteriocidal or bacteriostatic effects against *lactobacillus* as compared to *S. aureus* with *S. aureus* being more sensitive than *lactobacillus* (page 4, lines 28-35). The specification further asserts that *lactobacillus* exhibited strong growth in concentrations of hexahydro beta acids and tetrahydroiso alpha acids as high as 12.5 ppm, in contrast, *S. aureus* showed no to weak growth in the concentrations of the two hop acids as low as 1.56 ppm; and the sensitivity of *S. aureus* appeared to increase under acidic conditions, with the minimum inhibitory concentration (MIC) decreasing to 0.78 ppm at pH 6.0 and to less than 0.2 ppm at pH 5.0, and normally the pH of the vagina is about pH 4.5 to 5.0 (page 7, lines 8-18; Tables 1 and 2). However, the specification has not described the minimum inhibitory concentration of the two hop acids against *lactobacillus* at pH 4.5 to 5.0 (only at pH 6.3 in Table 2), nor has demonstrated the growth of *lactobacillus* at the concentration of 0.2 to 25 ppm of hexahydro beta acids and tetrahydroiso alpha acids at pH 4.5 to 5.0. Furthermore, the specification has not

indicated a product comprising an absorbent material and a compound of hexahydro beta acids, hexahydro beta salts, tetrahydroiso alpha acids or tetrahydroiso alpha salts, in an amount effective to kill, inhibit or control the growth of *S. aureus* without preventing the growth of *lactobacillus* at a pH of 4.5-5.0, and at the concentration of 0.2 to 25 ppm of the compound. The data shown Tables 1 and 2 indicate *S. aureus* is more sensitive toward the hop acids than *lactobacillus* at pH about 6, and at pH 6.3, the growth of *lactobacillus* species is not affected at 0.2-12.5 ppm (+++ growth), however, it appears the growth of *lactobacillus* species is affected to a certain degree at 25 ppm (+/- growth vs. +++ growth at 12.5 ppm). Since there is no data regarding the effect of hop acids on the growth of *lactobacillus* species besides at pH 6.3, it would be impossible to predict the effects of hexahydrocolupulone at a concentration of 0.2-25 ppm on the growth of *lactobacilli* species without further experimentation. The lack of description of the effect of the hop acids at concentrations of 0.2-25 ppm on the growth of *lactobacilli* at pH 4.5 to 5.0 as encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

In response, applicants indicate based on the guidance regarding the written description requirement as indicated in the Court of Appeals for the Federal Circuit (In *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320 (2000)), it must be decided in the present case whether "one skilled in the art, reading the original disclosure, [would] immediately discern the limitation at issue in the claims", and every limitation of claims 15 and22 can be found in the specification; Regarding the Examples of the present specification in assessing the written description requirement, the applicant may meet the written description requirement in parts of

the specification other than the Examples. Furthermore, the Court of Customs and Patent Appeals (*In re Strahilevitz*, 668 F.2d 1229, 1232 (1982)) note that "examples are not required to satisfy section 112, first paragraph" (pages 5-7 of the response).

Applicants response has been fully considered, however, the argument is not fully persuasive because while the specification indicates the product comprising an absorbent material and an amount of compound which effectively kills, inhibits or otherwise controls the growth or proliferation of *S. aureus* without preventing the growth of *lactobacillus* when said product is exposed to the *S. aureus* environment (page 5, lines 31-34), and normally, the pH of the vagina is in the range of about 4.5 to 5.0 (page 7, lines 17-18); the Example (the data in Tables 1 and 2) indicate the hop acids at 0.2-25 ppm kill the growth of *S. aureus* at pH 6.0 and 5.0, and at pH 6.3, the growth of *lactobacillus* species is affected to a certain degree at 25 ppm (+/- growth vs. +++ growth at 12.5 ppm), which is not consistent with the term "without preventing the growth of *lactobacillus*". Since there is no data indicating the effect of hop acids on the growth of *lactobacillus* species at pH 4.5-5.0, without guidance and teachings in the specification, and further experimentation, one skilled in the art would not recognize the hop acids at a concentration of 0.2-25 ppm would prevent the growth of *lactobacilli* species at pH 4.5-5.0.

Conclusion

5. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner

CMK
February 1, 2005